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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,257	03/21/2001	Nancy D. Hanson	180.00030102	6204

26813 7590 05/05/2004

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EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/814,257	HANSON ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *RCE filed on 4/2/2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-17,39-44,47-49 and 51-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12-16 and 51* is/are allowed.

6)☒ Claim(s) *17,39-44,47-49,53 and 54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE filed on April 2, 2004 and the amendment filed on March 11, 2004 have been entered. The claims pending in this application are claims 12-17, 39-44, 47-49, and 51-54. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on March 11, 2004.

Claim Objections

2. Claims 17 and 52-54 are objected to because of the following informalities: "using a primer that is complementary to each extension product" should be "using a primer that is complementary to said each extension product after separation from the beta-lactamase nucleic acid".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 39-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 39 recites the limitation "the OXA-9 beta-lactamase enzyme" in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no OXA-9 beta-lactamase enzyme in claim 17.

6. Claim 41 recites the limitation "the OXA-12 beta-lactamase enzyme" in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no OXA-12 beta-lactamase enzyme in claim 17.

7. Claim 43 recites the limitation "the OXA-5, 6, 7, 10, 11, 13, and 14 beta-lactamase enzymes" in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no OXA-5, 6, 7, 10, 11, 13, and 14 beta-lactamase enzymes in claim 17.

8. Claim 47 recites the limitation "the OXA-2, 3, and 15 beta-lactamase enzymes" in the claim. There is insufficient antecedent basis for this limitation in the claim since there is no OXA-2, 3, and 15 beta-lactamase enzymes in claim 17.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 17, 43, 53, and 54 are rejected under 35 U.S.C. 102(a) as being anticipated by Vahaboglu *et al.*, (J. Clin. Microbiology, 36, 827-829, March 1998).

Vahaboglu *et al.*, teach the detection and identification of OXA-10-derived ceftazidime-hydrolyzing extended-spectrum beta-lactamases in *Pseudomonas aeruginosa* isolates from clinical samples. PCR was designed to amplify a 720 bp fragment of beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 and PCR products from beta lactamase OXA-10, -17, -11, -14 and -16 were analyzed by gel electrophoresis in order to differentiate different OXA subtypes (see pages 827 and 828 and Figure 1)

Regarding claim 17, since Vahaboglu *et al.*, teach to amplify beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 and analyze PCR products from beta lactamases of OXA-10, -17, -11, -14 and -16 by gel electrophoresis in order to differentiate different OXA subtypes(see pages 827 and 828 and Figure 1), Vahaboglu *et al.*, disclose all method steps recited in claim 17. Although claim 17 requires a pair of oligonucleotide primers specific for nucleic acid encoding an OXA family beta-lactamase enzyme wherein the enzymes are found in a Gram-negative bacterium selected from the group of *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Escherichia coil, Providencia spp., Proteus mirabills, Yersinia enterocolitica,* and combinations thereof excluding OXA-1 and analyzing the separated amplified products for a region characteristic of a beta-lactamse, the claim does not limit that the nucleic acid used for amplification is a nucleic acid sequence from *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Escherichia coil, Providencia spp., Proteus mirabills,* and *Yersinia enterocolitica.* The claim merely requires a nucleic acid from OXA family beta-lactamase enzymes excluding OXA-1 and an OXA family beta-lactamase enzyme excluding OXA-1 can be found in a Gram-negative bacterium selected from the group of *Enterbacter cloacae, Cltrobacter freundii,*

Serratia marcescens, Escherichia coil, Providencia spp., Proteus mirabills, Yersinia enterocolitica, and combinations thereof. Therefore, Vahaboglu *et al.*, teach detection of an OXA family beta-lactamase enzyme excluding OXA-1 as claimed.

Regarding claim 43, since Vahaboglu *et al.*, teach to PCR amplify and analyze beta lactamase OXA-10, -17, -11, -14 and –16 (see pages 827 and 828 and Figure 1), claim 43 is anticipated by Vahaboglu *et al.*.

Regarding claim 53, although claim 53 requires that, when the oligonucleotide primers are specific for the OXA family beta-lactamase enzyme designated OXA-1, OXA-5, 6, 7, 10, 11, 13, or 14, OXA-9, OXA-12, and OXA-2, 3, or 15, the primers are selected from the group of SEQ ID NOs: 34-43, the method recited in claim 53 can also be performed when the primers are not selected from the group of SEQ ID NO: 34-43. Since Vahaboglu *et al.*, teach to amplify beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 and analyze PCR products from beta lactamases of OXA-10, -17, -11, -14 and -16 by gel electrophoresis in order to differentiate different OXA subtypes (see pages 827 and 828 and Figure 1), Vahaboglu *et al.*, disclose all limitations recited in claim 53.

Regarding claim 54, since Vahaboglu *et al.*, teach to amplify beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 and analyze PCR products from beta lactamases of OXA-10, -17, -11, -14 and -16 by gel electrophoresis in order to differentiate different OXA subtypes(see pages 827 and 828 and Figure 1), Vahaboglu *et al.*, disclose all method steps recited in claim 54. Although claim 17 requires a pair of oligonucleotide primers specific for nucleic acid encoding an OXA family beta-lactamase enzyme wherein the enzymes are found in a Gram-negative bacterium

selected from the group of *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Providencia spp., Proteus mirabills, Yersinia enterocolitica*, and combinations thereof and analyzing the separated amplified products for a region characteristic of a beta-lactamase, the claim does not limit that the nucleic acid used for amplification is a nucleic acid sequence from *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Providencia spp., Proteus mirabills,* and *Yersinia enterocolitica.* The claim merely requires a nucleic acid from OXA family beta-lactamase enzymes and an OXA family beta-lactamase enzyme can be found in a Gram-negative bacterium selected from the group of *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Providencia spp., Proteus mirabills, Yersinia enterocolitica*, and combinations thereof. Therefore, Vahaboglu *et al.*, teach detection of an OXA family beta-lactamase enzyme excluding OXA-1 as claimed.

Therefore, Vahaboglu *et al.*, teach the limitations recited by claims 17, 43, 53, and 54.

Response to Arguments

In page 11, second paragraph of applicant's remarks, applicant argues that "[T]hese claims have been amended to clarify that the primers used for amplification are specific for nucleic acid encoding an OXA family beta-lactamase enzyme found in a specific group of Gram-negative bacteria, thereby rendering this rejection moot.".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because the amendment filed on March 11, 2004 has not overcome the rejection (see above rejection under 35 USC 102 (a)).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vahaboglu *et al.*, (March, 1998) as applied to claims 17, 43, 53, and 54 above, and further in view of Tolmasky (Plasmid, 24, 218-226, 1990) as evidence by Tolmasky *et al.*, (Plasmid, 29, 31-40, 1993)

The teachings of Vahaboglu *et al.*, have been summarized previously, *supra.*

Vahaboglu *et al.*, do not disclose that the primers are specific for nucleic acid encoding OXA-9 beta-lactamase enzyme as recited in claim 39.

Tolmasky teaches a fragment of Tn 1331 having cDNA of TEM beta-lactamase (see Tolmasky, abstract in page 215, and Figures 2 and 3 in pages 220 and 221), which is an OXA- 9 beta-lactamase from E. coli (see Tolmasky *et al.*, page 32, left column and Figure 4 in page 37).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art

at the time the invention was made to have performed the method recited in claim 39 wherein the primers are specific for nucleic acid encoding OXA-9 beta-lactamase enzyme in view of the prior art of Vahaboglu *et al.*, and Tolmasky as evidence by Tolmasky et al.. One having ordinary skill in the art would have been motivated to do so because Vahaboglu *et al.*, have successfully amplified beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 and analyzed PCR products from beta lactamases of OXA-10, -17, -11, -14 and –16 and, and synthesis of primers specific for nucleic acid encoding OXA-9 beta-lactamase enzyme, based on known cDNA sequence of an OXA-9 beta-lactamase enzyme, and use of synthesized primers to perform the method recited in claim 39 in order to detect and identify ceftazidime-hydrolyzing extended-spectrum mutants from other OXA family beta-lactamase (ie., OXA-9) would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to perform the method recited in claim 39 using the primers specific for a nucleic acid encoding OXA-9 beta-lactamase enzyme.

13. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vahaboglu *et al.*, (March, 1998) as applied to claims 17, 43, 53, and 54 above, and further in view of Rasmussen *et al.*, (Antimicrobial Agents and Chemotherapy, 38, 2078-2085, September 1994) as evidence by Alksne *et al.*, (Journal of Bacteriology, 179, 2006-2013, March 1997)

The teachings of Vahaboglu *et al.*, have been summarized previously, *supra*.

Vahaboglu *et al.*, do not disclose that the primers are specific for nucleic acid encoding

OXA-12 beta-lactamase enzyme as recited in claim 41.

Rasmussen *et al.*, teach cDNA of asbB1 beta-lactamase from *Aeromonas sobria* ARE14 M (see Rasmussen *et al.*, abstract in page 2078, and Figure 3 in page 2083), which is an OXA-12 beta-lactamase (see Alksne *et al.*, page 2006, left column).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 41 wherein the primers are specific for nucleic acid encoding OXA-12 beta-lactamase enzyme in view of the prior art of Vahaboglu *et al.*, and Rasmussen *et al.*, as evidence by Alksne *et al.*. One having ordinary skill in the art would have been motivated to do so because Vahaboglu *et al.*, have successfully amplified beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 and analyzed PCR products from beta lactamases of OXA-10, -17, -11, -14 and –16 and, and synthesis of primers specific for nucleic acid encoding OXA-12 beta-lactamase enzyme, based on known cDNA sequence of an OXA-12 beta-lactamase enzyme, and use of synthesized primers to perform the method recited in claim 41 in order to detect and identify ceftazidime-hydrolyzing extended-spectrum mutants from other OXA family beta-lactamase (ie., OXA-12) would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to perform the method recited in claim 41 using the primers specific for a nucleic acid encoding OXA-12 beta-lactamase enzyme.

14. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vahaboglu *et al.*, (March, 1998) as applied to claims 17, 43, 53, and 54 above, and further in view of Danel *et al.*, (Antimicrobial Agents and Chemotherapy, 41, 785-790, April 1997).

The teachings of Vahaboglu *et al.*, have been summarized previously, *supra.*

Vahaboglu *et al.*, do not disclose that the primers are specific for nucleic acid encoding OXA-15 beta-lactamase enzyme as recited in claim 47.

Danel *et al.*, teach cDNA of OXA-15 beta-lactamase from a *Pseudomonas aeruginoas* strain (see page 785, abstract and page 788, Figure 3).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 47 wherein the primers are specific for nucleic acid encoding OXA-15 beta-lactamase enzyme in view of the prior art of Vahaboglu *et al.*, and Danel *et al.*. One having ordinary skill in the art would have been motivated to do so because Vahaboglu *et al.*, have successfully amplified beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 and analyzed PCR products from beta lactamases of OXA-10, -17, -11, -14 and –16, and synthesis of primers specific for nucleic acid encoding OXA-15 beta-lactamase enzyme, based on known cDNA sequence of an OXA-15 beta-lactamase enzyme, and use of synthesized primers to perform the method recited in claim 47 in order to detect and identify ceftazidime-hydrolyzing extended-spectrum mutants from other OXA family beta-lactamase (ie., OXA-15) would have been, in the absence of convincing evidence to the contrary, *prima facie* obvious to one having ordinary skill in the art at the time the invention was made. One having ordinary skill in the art at the time the invention was made

would have been a reasonable expectation of success to perform the method recited in claim 47 using the primers specific for a nucleic acid encoding OXA-15 beta-lactamase enzyme.

15. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vahaboglu *et al.*, (March, 1998) as applied to claims 17, 43, 53, and 54 above, and further in view of Fluit *et al.*, (WO91/08305, published on June 13, 1991).

The teachings of Vahaboglu *et al.*, have been summarized previously, *supra*. Since Vahaboglu *et al.*, teach to amplify beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 (see pages 827 and 828 and Figure 1) and the claim does not limit that the nucleic acid used for amplification is a nucleic acid sequence from *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Escherichia coil, Providencia spp., Proteus mirabills,* and *Yersinia enterocolitica*, Vahaboglu *et al.*, disclose (a) of the claim. Since Vahaboglu *et al.*, teach to amplify OXA beta lactamases from OXA positive isolates and OXA-negative isolates (see page 828, Figure 1), Vahaboglu *et al.*, disclose (b) of the claim. Since Vahaboglu *et al.*, teach the method for identify OXA beta lactamases by gel electrophoresis of digested PCR products of OXA beta lactamases and DNA sequencing of PCR products of OXA beta lactamases (see page 828), Vahaboglu *et al.*, disclose (c) of the claim.

Vahaboglu *et al.*, do not disclose a bacteria diagnostic kit as recited in the claim.

Fluit *et al.*, do teach a bacteria diagnostic kit (see pages 24 and 25).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have organized the components and method taught by Vahaboglu *et al.*, into a kit because the method for identifying a beta-lactamase in a bacteria

sample by analyzing PCR products of the beta-lactamase or sequencing of PCR products of the beta-lactamase was known at that time the inventions were made and the kit format was utilized not only to assemble a variety of different reagents together but ensured the quality and compatibility of the reagents. One having ordinary skill in the art at the time the invention was made would have been motivated to assemble reagent (s) of biotechnology methods into a kit in order to obtain the above discussed advantages, thus resulting in instant kit recited in claim 49. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to organize a kit recited in claim 49 because the kit would provide a convenient, efficient, economical way to practice the method of Vahaboglu *et al.*.

Response to Arguments

In page 11, third paragraph of applicant's remarks, applicant argues that "[C]laim 49 has been amended to clarify that the primers used for amplification are specific for nucleic acid encoding an OXA family beta-lactamase enzyme found in a specific group of Gram-negative bacteria, thereby rendering this rejection moot.".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because the amendment filed on March 11, 2004 has not overcome the rejection (see above rejection under 35 USC 103 (a)).

Conclusion

16. Claims 12-16 and 51 are allowed since SEQ ID Nos: 34-43 are free of prior art.

17. Claim 52 appears to be allowable if applicant can overcome above objection.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-9306 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
April 30, 2004

FRANK LU
PATENT EXAMINER